CareCore NATIONAL | MEDSOLUTIONS FTR

February 15, 2015

Senator Joseph Crisco
Co-Chair, Insurance and Real Estate Committee
Legislative Office Building, Room 2800
Hartford, CT 06106

Representative Robert Megna
Co-Chair, Insurance and Real Estate Committee
Legislative Office Building, Room 2802
Hartford, CT 06106

RE: House Bill 5832 and House Bill 6553

Senator Joseph Crisco, Representative Robert Megna and members of the Joint Committee on Insurance and Real Estate:

Thank you for the opportunity to comment on the challenges and potentially detrimental patient impacts of House Bill 5832 (HB 5832) and House Bill 6553 (HB 6553).

According to the American Cancer Society, more than 200,000 American women are diagnosed with breast cancer every year. While proper, proactive screening is a critical part of our fight against this disease, effective screening must be evidence-based, with robust clinical applications and guidelines to ensure patient welfare. Both HB 5832 and HB 6553 seek to cover procedures—digital breast tomosynthesis (DBT) and breast thermography, respectively—that have not been conclusively shown to improve clinical outcomes in breast cancer screening and diagnosis.

I have been the chief medical officer of MedSolutions, Inc. (now CareCore | MedSolutions) since 1996 and a board-certified family practice physician for the past 32 years. Our company uses the most up-to-date evidence-based clinical guidelines in all 50 states on behalf of 85 million Americans – approximately 1.2 million lives here in Connecticut – to ensure they get the proper care at the right time.

Medicine, and cancer screening in particular, must constantly weigh risks when it comes to patient care. Covering ineffective cancer screenings exposes patients to radiation and other risk factors. Nearly 30,000 excess cancers will result from the 72 million CT scans Americans received in 2007 alone, so these are not risk factors that should be taken lightly. As we note below, both DBT and thermography are unproven procedures that should not be covered by health insurance.

Challenges of HB 5832 and Covering DBT

Although there have been some promising performance metrics documented with regard to DBT, there is still a lack of evidence demonstrating its impact on long-term health outcomes. In addition, there are remaining questions regarding the appropriate clinical role of DBT, as well as which subgroups of women might benefit from these examinations. Until these issues are addressed and clarified, the medical community has a responsibility to continue to use screening practices that have been proven.

This is a view shared by the Connecticut Department of Social Services, which has stated that as of Feb. 4, 2015, the agency will discontinue coverage of DBT because "digital breast tomosynthesis has not been conclusively shown to improve clinical outcomes in breast cancer screening and diagnosis."[1]

More specifically, at this time, standards have not been developed for DBT as an imaging modality, and the FDA is not prepared to accredit 3D mammography. Additionally, evidentiary gaps still exist regarding which subgroups of women would benefit from this technology (e.g., breast density, patient age, etc.), the optimal frequency of DBT screening, as well as the long-term impact on clinical outcomes.

Also instructive are responses to a recent study reported in *The Journal of the American Medical Association* June 2014 issue. Breast imaging authorities weighing in noted that, "The nonrandomized design of the study by Friedewald et al precludes drawing causal inferences about the results, and the lack of long-term follow-up information limits the ability to provide definitive estimates of false-negative result rates, diagnostic accuracy, interval cancer rates, or overdiagnosis."

No randomized controlled trials, to date, have demonstrated the superiority of tomosynthesis over conventional mammography in long-term clinical outcomes.

Challenges of HB 6553 and Covering Thermography

The American Cancer Society says thermography is "not an effective screening tool for finding breast cancer early."[2] According to a 2012 research review by the organization, "thermography was able to detect only a quarter of the breast cancers found by mammography."[3]

Likewise, the Society of Breast Imaging does not support the use of thermography of the breast as either a screening tool in the detection of breast cancer or as an adjunctive diagnostic tool.

Claims of thermography as a "new" tool are also inaccurate. While technologies have developed, according to the ACS, "digital infrared thermal imaging (DITI), which some people believe is a newer and better type of thermography, has the same failure rate."[4]

---

[1] http://www.ct.gov/dss/lib/dss/pdfs/spa15017.pdf
[2]http://www.cancer.org/treatment/understandingyourdiagnosis/examsandtestdescriptions/mammogramsandotherbreastimagingprocedures/mammograms-and-other-breast-imaging-procedures-newer-br-imaging-tests
[3]http://www.cancer.org/treatment/understandingyourdiagnosis/examsandtestdescriptions/mammogramsandotherbreastimagingprocedures/mammograms-and-other-breast-imaging-procedures-newer-br-imaging-tests
[4]http://www.cancer.org/treatment/understandingyourdiagnosis/examsandtestdescriptions/mammogramsandotherbreastimagingprocedures/mammograms-and-other-breast-imaging-procedures-newer-br-imaging-tests

Conclusively, thermography does not work at any rate that would benefit patients or the providers working to diagnose them. Allowing coverage of a procedure that fails to work 75 percent of the time is dangerous and will significantly impact care.

For the reasons outlined above, I respectfully submit that these two pieces of legislation are not in the interests of Connecticut or its citizens and will significantly damage patient care while exposing them to potentially harmful radiation. Please do not hesitate to reach out if you have any questions or concerns.

Sincerely,

Gregg Allen, M.D., FAAFP
Executive Vice President and Chief Medical Officer
CareCore | MedSolutions

CC: Sen. Joan Hartley
Rep. David Zoni
Sen. Kevin Kelly
Rep. Robert Sampson
Rep. Catherine Abercrombie
Rep. Victor Cuevas
Rep. Jeff Currey
Rep. Stephen Dargan
Rep. Christopher Davis
Rep. Livvy Floren
Rep. Susan Johnson
Rep. Brenda Kupchick
Rep. Selim Nujaim
Rep. Emmett Riley
Rep. Christine Rosati
Rep. John Scott
Rep. Kurt Vail